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21

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,258	12/19/2001	Celal Albayrak	0081.02	2329
21968	7590	02/22/2005	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			WANG, SHENGJUN	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/028,258

Applicant(s)

ALBAYRAK, CELAL

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1617

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2004 has been entered.

#### ***Claim Rejections 35 U.S.C. 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 8-17, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. (WO 97/19676).

4. The instant invention is directed toward a process of making microparticles comprising dissolving a polymer in a halogen free solvent that partially water miscible, adding a hydrophilic active agent, mixing the two, and adding an aqueous surfactant and mixing.

5. Rossling et al. teach a method of producing morphologically uniform microcapsules. The method comprising dissolving biodegradable polymers in a halogen-free solvent or solvent mixture, and then dispersing into this solution, a buffered, hydrophilic active ingredient solution. Then, an aqueous solution that contains a surface-active substance is added to the emulsion, and the solvent is removed by vacuum. The microcapsules are taught as ranging in size from 200nm

Art Unit: 1617

to 500um. Polyglycolides, such as glycolide/lactide copolymers are taught as polymers. Acetone, ethanol, alkyl acetates, alkyl formates, triacetin, triethyl citrate, and/or alkyl lactates are taught as solvents. Tris(hydroxymethyl)aminomethane and citrate are taught as buffer solutions. Nonionic surfactants, polyethylene glycol, and others are taught as surfactants. The reference does not teach expressly the solubility parameters of the polymer solvent and the aqueous phase as less than zero and does not teach the preferred ratios of the polymer phase to the surfactant phase, And the volume fraction of the surfactant phase. US 6,294,204 relied upon as an English translation, and see particularly column 1-5 therein. Applicants' attention is also directed to the claims (pages 20-22) in WO97/19676, wherein no particular ratio of the polymer phase and surfactant phase is required.

6. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solubility parameters, ratios, and volumes of the polymer solvent and the aqueous phase of Rossling et al. because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Thus, one of skill in the art would be motivated to vary these parameters because of the expectation of achieving the most stable product, wherein the active ingredient is most efficiently and effectively delivered.

7. The Examiner respectfully point out instant claim 30 is a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

Art Unit: 1617

by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

See MPEP 2113. However, since claim 30 depends on claims 1, 5, 8, 24 or 26, claim 30 is not being rejected under 102(b), though such microparticles are known in the art.

8. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling et al. as applied to claims 1-17 and 20-30 above, and further in view of Setterstrom et al. (6,410,056).

Rossling et al. is applied as discussed above. The reference lacks microspheres and microsponges.

Setterstrom et al. teach that microspheres tend to be more difficult to rupture as compared to microcapsules because of their internal structure is stronger. Microsponges are taught as porous microspheres. See Col. 3, lines 44-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the microparticles of Rossling et al. into microspheres instead of microcapsules because of the expectation of achieving a formulation that is stronger and does not rupture as easily, thereby producing a formulation that is longer-lasting once ingested.

### ***Response to Arguments***

Applicants' amendments and remarks submitted October 21, 2004 have been fully considered, but are not persuasive as to the rejections set forth above.

The rejections set forth above are essentially the same as those set forth in the office action mailed April 21, 2004. Applicants traverse those rejections on following grounds: Rossling does not teach more than 60% v/v of surfactant phase as herein required, and Rossling particular claims less than 60% v/v of surfactant phase in the US patent. The examiner respectfully points

Art Unit: 1617

out that though less than 60% v/v of surfactant phase was claimed in USD patent, the reference as a whole does not require such limitation for practice the method disclosed therein. Attention is directed to the claims of WO97/19676 (pages 20-22), wherein no particular ratio of polymer phase and surfactant phase is required. Thus, it would be within the skill of the artisan in the microparticle art to optimize the volumes, and hence, solubility parameters, to achieve that recited in the instant claims. It is respectfully pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, It has been held that discovering an optimal value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).


9. Applicants further argue that the method disclosed by Rossling requires the removal of solvent to form microparticles, which is not required in the pending claims. First, it is noted that the instant claims employ the transitional phrase “comprising” which is open to any additional steps. Second, claim 2 herein does involving the removal of solvent. Third, the total steps recited by Rossling are for the produce of the final product microcapsulate, not forming microcapsulate. It would have reasonably expected that the microcapsulates are formed be for the steps of solvent removal since the solvent is expected to be extracted to the aqueous phase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**SHENGJUN WANG**  
**PRIMARY EXAMINER**

Shengjun Wang  
Primary Examiner  
Art Unit 1617

1.